

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

This Amendment is filed concurrently with a request for continued prosecution ("RCE") and an information disclosure statement, and is filed in response to the Office Action and Notice. The RCE and Amendment are being filed in lieu of an appeal brief.

The Office Action requested cancellation of claims 19 – 22 drawn to a nonelected invention; objected to the Specification under 35 USC §112, first paragraph, as being non-enabling; rejected claims 23 – 24 under 35 USC §112, first paragraph, as being non-enabling; rejected claims 1 – 2, 10 – 11, 23 and 24 under 35 USC §103 as being unpatentable over United States Patent No. 6,245,797 to Winokur ("Winokur") in view of the abstract to Mitchell, et al., 90(24) Proceedings of the National Academy of Sciences of the USA 11693-7 (1993) ("Mitchell Abstract"); and rejected claims 3 – 9 and 12 – 18 under 35 USC §103 as being unpatentable over Winokur in view of the Mitchell Abstract, and further in view of United States Patent No. 5,07,834 to Morehouse ("Morehouse"), Pick et al. abstract ("Pick Abstract"), and Sun et al. abstract ("Sun"). Complete copies of the references summarized in the Mitchell Abstract and the Pick Abstract, respectively, are included in the information disclosure reference filed simultaneously herewith.

As requested in the Office Action, claims 19 – 22 were cancelled without prejudice or disclaimer to the subject matter contained therein and without

prejudice or disclaimer to the refiling of these claims in a continuation application because claims 19 - 22 are directed to a nonelected invention. For purposes of expediting the prosecution, claims 23 and 24 were also cancelled without prejudice or disclaimer to the subject matter contained therein and without prejudice or disclaimer to the refiling of these claims in a continuation application. In view of the cancellation of these claims, Applicants respectfully submit that the objection to the Specification and the rejection of claims 23 and 24 under 35 USC §112, first paragraph, has been overcome and should be withdrawn.

Claims 1 – 18 are pending in this application after entry of this Amendment.

The Rejection of Claims 1 – 2, 10 – 11, 23 and 24 Under 35 USC §103(a) Based on Winokur in view of the Mitchell Abstract Has Been Overcome.

Claims 1 – 2, 10 – 11, and 23 - 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Winokur in view of the Mitchell Abstract. Applicants respectfully disagree in view of the ensuing discussion.

Winokur teaches the combination of an HMG-CoA reductase inhibitor in combination with a COX-2 inhibitor for treating atherosclerosis. See Winokur, Column 2, lines 55 – 59. According to the Office Action, Winokur fails to “recite the specific COX-2 inhibitor as useful for the anti-atherosclerotic use.” The Office Action further maintained that the Mitchell Abstract allegedly taught that acetaminophen was “an old and well known inhibitor of cyclooxygenase enzymes, specifically COX-2,” and thus one skilled in the art would allegedly

“have been motivated to employ the COX-2 inhibitors taught by Mitchell” for use in arteriosclerosis. Applicants respectively submit that acetaminophen (APAP) is not a known inhibitor of cyclooxygenase, let alone a known inhibitor of COX-2, and that one skilled in the art would not be motivated to select APAP as an example of a COX-2 inhibitor suitable for use in the atherosclerotic treatment of Winokur.

According to Winokur, COX-2 inhibitors are “compounds which selectively inhibit cyclooxygenase-2 over cyclooxygenase-1.” See Winokur, column 5, lines 35 – 38 (emphasis added). However, as provided in the Mitchell Abstract, “acetaminophen [was] approx. equipotent inhibitors of COX-1 and COX-2 in intact cells.” (emphasis added). Therefore, based upon the definition of “COX-2 inhibitor” as provided by Winokur, Applicants respectfully submit that APAP cannot be considered as a COX-2 inhibitor.

Applicants further respectfully submit that one skilled in the art would therefore not be motivated to combine APAP, which according to the definition of Winokur is not a COX-2 inhibitor, with the HMG-CoA reductase inhibitor of Winokur for use in the treatment of atherosclerosis.

In sum, because the Mitchell Abstract fails to disclose or suggest that APAP is a COX-2 inhibitor as defined in Winokur and because there then is no motivation to combine APAP with the HMG-CoA reductase inhibitor of Winokur for use in the treatment of atherosclerosis, Applicants respectfully submit that the rejection of claims 1 – 2, 10 – 11, and 23 to 24 under 35 USC §103 has been overcome and should be withdrawn.

The Rejection of Claims 3 – 9 and 12 – 18 Under 35 USC §103 Based on Winokur in view of the Mitchell Abstract, and further in view of Morehouse, Pick Abstract , and Sun Has Been Overcome.

Claims 3 – 9 and 12 - 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Winokur in view of the Mitchell Abstract, and further in view of Morehouse, Pick Abstract , and Sun. Applicants respectfully disagree in view of the ensuing discussion.

Applicants respectfully submit that claims 3 – 9 and 12 – 18, which are dependent upon independent claim 1 and incorporate all of its limitations therein, are patentable for the reasons set forth above.

Further, Morehouse teaches the use of a combination of a specific cholesterol absorption inhibitor (see e.g., Morehouse, column 53, line 45 – column 55, line 54) with a HMG-CoA reductase inhibitor, the latter of which may be atorvastatin (see Id., column 55, lines 54 – 61 and claim 18). These combinations may be used to treat atherosclerosis. See Id., Abstract. However, Morehouse neither discloses nor suggests the combination of acetaminophen with atorvastatin, let alone the combination of acetaminophen with atoravastatin for treatment of atherosclerosis.

Sun teaches the use of vitamins C and E for use in decreasing the “incidence of arteriosclerosis induced by cholesterol.” However, Sun neither discloses nor suggests the combination of acetaminophen with vitamins C and E, let alone the combination of acetaminophen with vitamins C and E for treatment of atherosclerosis.

Pick Abstract teaches the use of aspirin for use in decreasing the “primary prevention of diet-induced coronary atherosclerosis.” However, Pick neither discloses nor suggests the combination of acetaminophen with aspirin, let alone the combination of acetaminophen with aspirin for treatment of atherosclerosis.


In sum, one skilled in the art who was looking to treat atherosclerosis would not be motivated to combine acetaminophen with vitamins C or E, aspirin, or atorvastatin in the treatment dose

In view of the fact that the cited references, either alone or in combination, fail to disclose or suggest the treatment of atherosclerosis via use of the claimed acetaminophen and secondary agent combinations, Applicants respectfully submit that the rejection of claims 3 – 9 and 12 – 18 under 35 USC §103 as being unpatentable over Winokur in view of Mitchell Abstract, and further in view of Morehouse, Pick Abstract and Sun has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

By: 
Michele G. Mangini
(Attorney for Applicants)
Reg. No. 36,806
Dated: 13 January 2003

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2810
Mcp267.amt.3.2004.doc